



Commonwealth of Massachusetts
Executive Office of Energy & Environmental Affairs

Department of Environmental Protection

Northeast Regional Office • 205B Lowell Street, Wilmington MA 01887 • 978-694-3200

DEVAL L. PATRICK
Governor

RICHARD K. SULLIVAN JR.
Secretary

DAVID W. CASH
Commissioner

Date stamped June 5, 2014

Ms. Brenda DeLouchrey
St. Jude Medical, Inc.
4 Robbins Road
Westford, MA 01886

RE: WESTFORD
Transmittal No.: X259340
Application No.: *NE-14-006*
Class: *BLWAQ*
FMF No.: 537957
**AIR QUALITY PLAN
APPROVAL**

Dear Ms. DeLouchrey:

The Massachusetts Department of Environmental Protection (“MassDEP”), Bureau of Waste Prevention, has reviewed your Limited Plan Application (“Application”) listed above. This Application concerns your proposal to manufacture medical devices, which will result in emissions of volatile organic compounds (VOC) and non-criteria air contaminants at your existing facility located at 4 Robbins Road, Westford, Massachusetts (“Facility”).

This Application was submitted in accordance with 310 CMR 7.02 Plan Approval and Emission Limitations as contained in 310 CMR 7.00 “Air Pollution Control,” regulations adopted by MassDEP pursuant to the authority granted by Massachusetts General Laws, Chapter 111, Section 142 A-J, Chapter 21C, Section 4 and 6, and Chapter 21E, Section 6. MassDEP’s review of your Application has been limited to air pollution control regulation compliance and does not relieve you of the obligation to comply with any other regulatory requirements.

MassDEP has determined that the Application is administratively and technically complete and that the Application is in conformance with the Air Pollution Control regulations and current air pollution control engineering practice, and hereby grants this **Plan Approval** for said Application, as submitted, subject to the conditions listed below.

Please review the entire Plan Approval, as it stipulates the conditions with which the Facility owner / operator (“Permittee”) must comply in order for the Facility to be operated in compliance with this Plan Approval.

1. DESCRIPTION OF FACILITY AND APPLICATION

St. Jude Medical, Inc. (“the Permittee”) currently manufactures medical devices at its Facility that use Optical Coherence Tomography to produce high resolution coronary images that are used by physicians to treat coronary artery disease. Permittee’s Emission Units (EUs) EU2, EU3, EU4, and EU5 (fully described in the Application) emit fugitive VOC emissions mainly from isopropyl alcohol (IPA), during manufacturing processes. The Permittee’s EU1 emits a small quantity of sulfuric acid. All air contaminant emissions from the Permittee’s Facility have been limited in a legally enforceable manner. See Table 2 below.

2. EMISSION UNIT (EU) IDENTIFICATION

The Emission Units (EUs) identified in Table 1 are subject to and regulated by this Plan Approval:

| Table 1 | | | |
|----------------|-----------------------------------|------------------------|---------------------------------------|
| EU# | Description | Design Capacity | Pollution Control Device (PCD) |
| EU1 | Optical Fiber Cladding Stripping | NA | None |
| EU2 | Ultrasonic Cleaning of Fiber Ends | NA | None |
| EU3 | Fiber Splicing and Polishing | NA | None |
| EU4 | Catheter Wipe Down | NA | None |
| EU5 | Hydrophilic Coating | NA | None |

Table 1 Key:

EU = Emission Unit

= Number

PCD = Pollution control device

VOC = Volatile organic compounds

NA = Not applicable

3. APPLICABLE REQUIREMENTS

A. OPERATIONAL, PRODUCTION AND EMISSION LIMITS

The Permittee is subject to, and shall not exceed the Operational, Production, and Emission Limits as contained in Table 2, below:

| Table 2 | | | | |
|-------------------|-----------------------------------|-----------------|----------------|------------------|
| EU# | Operational / Production Limit | Air Contaminant | Emission Limit | |
| | | | Monthly | 12-month Rolling |
| (tons) | | | | |
| EU1 | N/A | Sulfuric Acid | 0.02 | 0.1 |
| EU2 | N/A | VOC | 0.46 | 2.8 |
| EU3 | N/A | VOC | 0.07 | 0.4 |
| EU4 | N/A | VOC | 0.15 | 0.9 |
| EU5 | N/A | VOC | 0.12 | 0.7 |
| Facility- wide | | VOC | 0.9 | 4.8 |
| | | Sulfuric acid | 0.02 | 0.1 |

Table 2 Key:

EU# = Emission Unit Number

VOC = Volatile Organic Compounds

N/A = Not applicable

B. COMPLIANCE DEMONSTRATION

The Permittee is subject to, and shall comply with, the monitoring, testing, record keeping, and reporting requirements as contained in Tables 3, 4, and 5 below:

| Table 3 | |
|----------------|---|
| EU# | Monitoring and Testing Requirements |
| EU2-EU5 | 1. Monitor usage of VOC containing cleaners/adhesives at the Facility and VOC content of each cleaner/adhesive used at the Facility on a monthly basis such that the Facility's actual emissions of VOC can be used to determine compliance status with the emission limits contained in Table 2 above. |
| EU1 | 2. Monitor usage of sulfuric acid used at the Facility on a monthly basis such that the Facility's actual emissions of sulfuric acid can be used to determine compliance status with the emission limits contained in Table 2 above. |
| Facility-wide | 2. If and when MassDEP requires it, the Permittee shall conduct emission testing in accordance with USEPA Reference Test Methods and Regulation 310 CMR 7.13. |

Table 3 Key:

EU# = Emission Unit Number

VOC = Volatile Organic Compounds

MassDEP = Massachusetts Department of Environmental Protection

USEPA = United States Environmental Protection Agency

| Table 4 | |
|---------------|--|
| EU# | Record Keeping Requirements |
| Facility-wide | 1. The Permittee shall maintain adequate records on-site to demonstrate compliance status with all emission limits contained in Table 2 above. Records shall include the actual emissions of air contaminant(s) emitted for each calendar month and for each consecutive twelve month period (current month plus prior eleven months). These records shall be compiled no later than the 15 th day following each month. An electronic version of the MassDEP approved record keeping form, in Microsoft Excel format, can be downloaded at http://www.mass.gov/dep/air/approvals/aqforms.htm#report . |
| | 2. The Permittee shall maintain records of monitoring and testing as required by Table 3. |
| | 3. The Permittee shall maintain a copy of this Plan Approval, underlying Application and the most up-to-date SOMP's for the EUs approved herein on-site. |
| | 4. The Permittee shall maintain a record of routine maintenance activities performed on the approved EUs. The records shall include, at a minimum, the type or a description of the maintenance performed and the date and time the work was completed. |
| | 5. The Permittee shall maintain a record of all malfunctions affecting air contaminant emission rates on the approved EUs. At a minimum, the records shall include: date and time the malfunction occurred; description of the malfunction; corrective actions taken; the date and time corrective actions were initiated and completed; and the date and time emission rates returned to compliant operation. |
| | 6. The Permittee shall maintain records required by this Plan Approval on-site for a minimum of five (5) years. |
| | 7. The Permittee shall make records required by this Plan Approval available to MassDEP and USEPA personnel upon request. |

Table 4 Key:

EU# = Emission Unit Number

EUs = emission units

SOMP's = Standard Operating and Maintenance Procedures

MassDEP = Massachusetts Department of Environmental Protection

USEPA = United States Environmental Protection Agency

| Table 5 | |
|---------------|---|
| EU# | Reporting Requirements |
| Facility-wide | 1. The Permittee shall submit to MassDEP all information required by this Plan Approval over the signature of a “Responsible Official” as defined in 310 CMR 7.00 and shall include the Certification statement as provided in 310 CMR 7.01(2)(c). |
| | 2. The Permittee shall notify the Northeast Regional Office of MassDEP, BWP Permit Chief by email at nero.air@state.ma.us or fax 978-694-3499 as soon as possible, but no later than one (1) business day after discovery of any exceedance(s) of Table 2 requirement(s). A written report shall be submitted to the BWP Permit Chief within three (3) business days thereafter and shall include: identification of exceedance(s), duration of exceedance(s), reason for the exceedance(s), corrective actions taken, and action plan to prevent future exceedance(s). |
| | 3. The Permittee shall provide a copy to MassDEP of any record required to be maintained by this Plan Approval upon request. |
| | 4. The Permittee shall submit to MassDEP for approval a stack emission pretest protocol, at least 60 days prior to emission testing, for any emission testing as defined in Table 3 Monitoring and Testing Requirements. |
| | 5. The Permittee shall submit to MassDEP a final stack emission test results report, within 45 days after emission testing, for any emission testing as defined in Table 3 Monitoring and Testing Requirements. |

Table 5 Key:

EU# = Emission Unit Number

CMR = Code of Massachusetts Regulations

MassDEP = Massachusetts Department of Environmental Protection

BWP = Bureau of Waste Prevention

3. SPECIAL TERMS AND CONDITIONS

The Permittee is subject to, and shall comply with, the following special terms and conditions:

- A. The Permittee shall comply with the Special Terms and Conditions as contained in Table 6 below:

| Table 6 | |
|----------------|--|
| EU# | Special Terms and Conditions |
| EU1-EU5 | 1. The Permittee shall follow the Standard Operating and Maintenance Procedures for the subject emission units so as to maintain efficient operation and minimize emissions of VOC and sulfuric acid. |
| Facility-wide | 3. All VOC containing raw material, waste, and cleaning rags used in conjunction with cleaning and sterilization shall be placed in tightly covered containers when not in use, and shall be collected for proper recycling or disposal. |
| | 4. All VOC and sulfuric acid containing material shall be transported and stored in tightly covered containers. Any emissions associated with surface preparation and /or cleanup solutions shall be included in the monthly and 12 month rolling emissions calculations to determine the Permittee's compliance status with emission limits contained in Table 2 above. |

Table 6 Key:

EU# = Emission Unit Number

VOC = Volatile Organic Compounds

- B. The Permittee shall install and use an exhaust stack, as required in Table 7, on Emission Unit that is consistent with good air pollution control engineering practice and that discharges so as to not cause or contribute to a condition of air pollution. Exhaust stack shall be configured to discharge the gases vertically and shall not be equipped with any part or device that restricts the vertical exhaust flow of the emitted gases, including but not limited to rain protection devices known as "shanty caps" and "egg beaters." The Permittee shall install and utilize exhaust stack with the following parameters, as contained in Table 7 below, for the Emission Unit that are regulated by this Plan Approval:

| Table 7 | | | | | |
|----------------|---|---------------------------------------|--|--|--|
| EU# | Stack Height Above Ground (feet) | Stack Height Above Roof (feet) | Stack Inside Exit Dimensions <i>in feet</i> | Stack Gas Exit Velocity Range (feet per second) | Stack Gas Exit Temperature Range (°F) |
| EU1 | 32 | 11.33 | 1.16 | 3226 | 70 |

Table 7 Key:

EU# = Emission Unit Number

°F = Degree Fahrenheit

6. GENERAL CONDITIONS

The Permittee is subject to, and shall comply with, the following general conditions:

- A. Pursuant to 310 CMR 7.01, 7.02, 7.09 and 7.10, should any nuisance condition(s), including but not limited to smoke, dust, odor or noise, occur as the result of the operation of the Facility, then the Permittee shall immediately take appropriate steps including shutdown, if necessary, to abate said nuisance condition(s).
- B. If asbestos remediation/removal will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that all removal/remediation of asbestos shall be done in accordance with 310 CMR 7.15 in its entirety and 310 CMR 4.00.
- C. If construction or demolition of an industrial, commercial or institutional building will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that said construction or demolition shall be done in accordance with 310 CMR 7.09(2) and 310 CMR 4.00.
- D. Pursuant to 310 CMR 7.01(2)(b) and 7.02(7)(b), the Permittee shall allow MassDEP and/or USEPA personnel access to the Facility, buildings, and all pertinent records for the purpose of making inspections and surveys, collecting samples, obtaining data, and reviewing records.
- E. This Plan Approval does not negate the responsibility of the Permittee to comply with any other applicable Federal, State, or local regulations now or in the future.
- F. Should there be any differences between the Application and this Plan Approval, the Plan Approval shall govern.
- G. Pursuant to 310 CMR 7.02(3)(k), MassDEP may revoke this Plan Approval if the construction work is not commenced within two years from the date of issuance of this Plan Approval, or if the construction work is suspended for one year or more.
- H. This Plan Approval may be suspended, modified, or revoked by MassDEP if MassDEP determines that any condition or part of this Plan Approval is being violated.
- I. This Plan Approval may be modified or amended when in the opinion of MassDEP such is necessary or appropriate to clarify the Plan Approval conditions or after consideration of a written request by the Permittee to amend the Plan Approval conditions.

- J. Pursuant to 310 CMR 7.01(3) and 7.02(3)(f), the Permittee shall comply with all conditions contained in this Plan Approval. Should there be any differences between provisions contained in the General Conditions and provisions contained elsewhere in the Plan Approval, the latter shall govern.

7. MASSACHUSETTS ENVIRONMENTAL POLICY ACT

MassDEP has determined that the filing of an Environmental Notification Form (ENF) with the Secretary of Energy & Environmental Affairs, for air quality control purposes, was not required prior to this action by MassDEP. Notwithstanding this determination, the Massachusetts Environmental Policy Act (MEPA) and 301 CMR 11.00, Section 11.04, provide certain “Fail-Safe Provisions,” which allow the Secretary to require the filing of an ENF and/or an Environmental Impact Report (EIR) at a later time.

8. APPEAL PROCESS

This Plan Approval is an action of MassDEP. If you are aggrieved by this action, you may request an adjudicatory hearing. A request for a hearing must be made in writing and postmarked within twenty-one (21) days of the date of issuance of this Plan Approval.

Under 310 CMR 1.01(6)(b), the request must state clearly and concisely the facts, which are the grounds for the request, and the relief sought. Additionally, the request must state why the Plan Approval is not consistent with applicable laws and regulations.

The hearing request along with a valid check payable to the Commonwealth of Massachusetts in the amount of one hundred dollars (\$100.00) must be mailed to:

Commonwealth of Massachusetts
Department of Environmental Protection
P.O. Box 4062
Boston, MA 02211

This request will be dismissed if the filing fee is not paid, unless the appellant is exempt or granted a waiver as described below. The filing fee is not required if the appellant is a city or town (or municipal agency), county, or district of the Commonwealth of Massachusetts, or a municipal housing authority.

MassDEP may waive the adjudicatory hearing-filing fee for a person who shows that paying the fee will create an undue financial hardship. A person seeking a waiver must file, together with

the hearing request as provided above, an affidavit setting forth the facts believed to support the claim of undue financial hardship.

Should you have any questions concerning this Plan Approval, please contact Mr. Dhiraj Desai by telephone at 978-694-3282, or in writing at the letterhead address

Sincerely,

This final document copy is being provided to you electronically by the
Department of Environmental Protection. A signed copy of this document
is on file at the DEP office listed on the letterhead.

Dhiraj B. Desai
Environmental Engineer

This final document copy is being provided to you electronically by the
Department of Environmental Protection. A signed copy of this document
is on file at the DEP office listed on the letterhead.

James E. Belsky
Permit Chief
Bureau of Waste Prevention

ecc: Health Department, 55 Main Street, Westford, MA 01886
Fire Department, 51 Main Street, Westford, MA 01886
MassDEP/Boston - Yi Tian
MassDEP/NERO – Marc Altobelli, M. Persky, D. Desai